IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

AVENTIS PHARMA DEUTSCHLAND GMBH and
KING PHARMACEUTICALS, INC.,
Plaintiffs

v. **Civil Action No. 2:05cv421**

LUPIN LTD. and
LUPIN PHARMACEUTICALS, INC.
Defendants.

MEMORANDUM OPINION AND ORDER

In this case, Plaintiffs Aventis Pharma Deutschland GMBH ("Aventis") and King Pharmaceuticals, Inc. ("King") have brought a two-count suit against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. for patent infringement and inducement of infringement. Presently before the Court is Defendants' motion for judgment on the pleadings under Fed. R. Civ. P. 12(c), asking this Court to dismiss Plaintiffs' willful infringement claim. For the reasons stated herein, Defendants' motion is **GRANTED** and the Court **DISMISSES** Plaintiffs' willful infringement claim **WITHOUT PREJUDICE** to the Court's ability to consider the "totality of circumstances" should the Court determine this is an "exceptional case" and fees are merited pursuant to 35 U.S.C. § 285 at the conclusion of this litigation.

I. Background

Plaintiff Aventis owns U.S. Patent No. 5,061,722, known as the "'722 patent." The '722 patent involves a pharmaceutical compound known as "ramipril" that is used to treat high blood pressure. Co-plaintiff King, the exclusive licensee of the '722 patent, markets ramipril under the trade name "ALTACE."

On March 18, 2005, Lupin Ltd., a generic drug company, submitted an "Abbreviated New Drug Application" ("ANDA") to the Food and Drug Administration (FDA) seeking approval to market generic versions of the ramipril capsules developed by Aventis. Pursuant to the ANDA content requirements established in 21 U.S.C. § 355(b) relating to the status of the "pioneer" patent, Lupin Ltd. certified that Plaintiffs' patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" under paragraph IV of the provision, which is commonly known as "paragraph IV certification." See § 355(b)(2)(A)(iv); Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1352 (Fed. Cir. 2003). As required by 21 U.S.C. § 355(j)(2)(B), Lupin Ltd. also sent a notification letter to Plaintiffs about its ANDA application on June 8, 2005.

After receiving the notification letter from Lupin Ltd., Plaintiffs subsequently filed suit in this Court on July 19, 2005. On August 29, 2005, Plaintiffs then filed an Amended Complaint containing two counts. With respect to Count 1, their patent infringement claim, Plaintiffs allege:

- Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use and sale of Lupin's Ramipril Capsules, prior to the expiration of the '722 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2). Pl.'s Am. Compl. ¶ 20.

- Unless enjoined by this Court, Lupin, upon FDA approval of Lupin's ANDA, will infringe the '722 patent by making, using, offering to sell, importing, and selling Lupin's Ramipril Capsules in the United States. Id. ¶ 21.

- Lupin had notice of the '722 patent at the time of its infringement. Lupin's infringement has been, and continues to be, willful and deliberate. Id. ¶ 23.

- Lupin's Paragraph IV Certification that, in Lupin's opinion, the '722 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of Lupin's Ramipril Capsules is baseless. Id. ¶ 24.

- This case is an exceptional one, and King and Aventis are entitled to an award of their reasonable attorney's fees under 35 U.S.C. § 285. Id. ¶ 25.

- Plaintiffs will be substantially and irreparably damaged and harmed if Lupin's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law. Id. ¶ 26.

With respect to Count 2, their inducing infringement claim, Plaintiffs allege "[u]pon information and belief, Lupin Pharmaceuticals, Inc. has infringed the '722 patent under 35 U.S.C. § 271(b) by actively inducing Lupin Ltd. to infringe the '722 patent." Id. ¶ 28. Plaintiffs conclude their complaint by requesting the following relief:

1. A judgment declaring that Lupin has infringed, and that Lupin's making, using, selling, offering to sell or importing Lupin's Ramipril Capsules and/or its active ramipril ingredient will infringe the '722 patent;

2. A judgment ordering that the effective date of any FDA approval for Lupin to make, use or sell Lupin's Ramipril Capsules be no earlier than the date on which the '722 patent expires, and expiration of any FDA exclusivities relating to King's ALTACE® drug products;

3. A judgment permanently enjoining Lupin from making, using, selling, offering to sell, or importing Lupin's Ramipril Capsules and/or its active ramipril ingredient until after the expiration of the '722 patent and any FDA exclusivities relating to King's ALTACE® drug products;

4. If Lupin engages in the commercial manufacture, use, offer to sell, or sale of Lupin's Ramipril Capsules and/or its active ramipril ingredient prior to the expiration of the '722 patent, a judgment awarding [P]laintiffs damages resulting from such infringement, increased to treble the amount found assessed, together with interest;

5. Attorney's fees in this action pursuant to 35 U.S.C. § 285;

6. Costs and expenses in this action; and

7. Such further and other relief as this Court may deem just and proper.

Id. ¶¶ (A)-(G).

On December 13, 2005, Defendants filed the present Rule 12(c) motion for judgment on the pleadings dismissing Plaintiffs' willful infringement claim. Plaintiffs filed their Memorandum in Opposition on December 27, 2005. Plaintiffs replied on December 30, 2005. The motion is therefore ripe for judicial determination.

II. Discussion

A. Standard of Review

Judgment on the pleadings, as provided by Fed. R. Civ. P. 12(c),[1] "authorizes resolution of a matter where no genuine issues of material fact remain and the moving party is entitled to judgment as a matter of law." Zeran v. America Online, Inc., 958 F. Supp. 1124, 1128 (E.D. Va. 1997). When reviewing a Rule 12(c) dismissal, "the allegations in the complaint are construed favorably to the plaintiff." Bruce v. Riddle, 631 F.2d 272, 273-74 (4th Cir. 1980). "All reasonable inferences" are thus drawn in favor of the plaintiff, Zeran, 958 F. Supp. at 1128, and a court must "find beyond a doubt that the plaintiff could prove no set of facts in support of his claim which would entitle him to relief." Bruce, 631 F.2d at 274. Because a Rule 12(c) motion tests the sufficiency of a claim, it "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." United States v. 328 Pounds More or Less, of Wild American Ginseng, 347 F. Supp. 2d

[1]Fed. R. Civ. P. Rule 12(c), Motion for Judgment on the Pleadings, provides:

> After the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings. If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.

241, 244 (W.D.N.C. 2004) (quoting Republican Party of North Carolina v. Martin, 980 F.2d 943, 952 (4th Cir.1992) (internal brackets omitted)). Accordingly, in order for a defendant's Rule 12(c) motion to succeed, the plaintiff must be precluded from recovering on his claim as a matter of law even if the pleadings were taken as true and construed in a light most favorable to the plaintiff. Zeran, 958 F. Supp. at 1128.

B. Analysis

1. The Parties' Arguments

In this case, Defendants argue that Plaintiffs' allegations cannot support a claim for willful infringement as a matter of law. Def.'s Mem. in Supp. of its Rule 12(c) Motion at 4. Citing paragraphs 20 and 23 of Plaintiff's Amended Complaint, Defendants maintain "Plaintiffs allege that Lupin Ltd. willfully infringes the '722 patent based solely on the filing of Lupin Ltd.'s ANDA and paragraph IV certification with the FDA" even though "the Federal Circuit . . . has specifically ruled that such allegations cannot support a finding of willful infringement." Id. at 4. In Defendants' view, "the Amended Complaint simply contains no allegations that could support a finding of willful infringement." Id. at 5.

Plaintiffs respond by noting that their Amended Complaint alleges that Defendants' infringement was "willful and deliberate" in paragraph 23, that their paragraph IV certification is "baseless" in paragraph 24, and that the case is "an exceptional one" in paragraph 25. Pl.'s Mem. in Opp. to Def.'s Rule 12(c) Motion at 3. Contending that Defendants misapply Glaxo Group, Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004) and Yamanouchi Pharm. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir. 2000), Plaintiffs urge that, because they have alleged more than willful infringement by alleging that the paragraph IV certification is "baseless" and that Defendants have

acted deliberately and in bad faith, they are entitled to develop and prove these allegations at trial.

2. The Hatch-Waxman Act, Willful Infringement, and Exceptional Cases

The ANDA application procedure was created by Congress in 1984, under what is commonly known as the "Hatch-Waxman Act." See 21 U.S.C. § 355; Warner-Lambert Co., 316 F.3d at 1352. The Act was a "compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory process; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements." Id. at 1358. The Act, and the ANDA application process it created, is thus designed to accomplish the following: 1) exempt generic drug manufacturers from infringement actions when researching and developing a generic version of a patented drug before the patent has expired, and 2) provide the innovative drug manufacturer the opportunity to protect its patent by allowing it to bring an infringement action pursuant to the generic company's ANDA filing to determine whether the generic drug, if marketed, would infringe the patent. Id.

To accomplish these goals, one primary purpose of the ANDA filing is to create a "highly artificial" act of infringement to allow for subject matter jurisdiction in a district court to resolve any disputes about infringement before the generic drug is sold. Eli Lily and Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990). The purpose "is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004). Indeed, the "paragraph IV" certification at issue here, one of four possible required certifications under the statute, demonstrates the anticipatory nature of the dispute, as generic companies must certify in their ANDA

application the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." See § 355(b)(2)(A)(iv) (emphasis added); see also Warner-Lambert, 316 F. 3d at 1352. Accordingly, filing an ANDA application is not a willful act of infringement in and of itself precisely because the ultimate finding of infringement involves an analysis of whether the patent will be infringed if the drug is made or marketed – "the inquiries are hypothetical." Id. at 1365. The hypothetical nature of the suit is also why "[t]his highly artificial act of infringement gives rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4)" if actual infringement is shown. Id.

Under 35 U.S.C. § 271(e)(4), the remedies available to a plaintiff that successfully protects its patent in ANDA cases are:

> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.
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> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

Section 285, which applies to all patent infringement cases generally, provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285

(emphasis added). When assessing whether a case is "exceptional," courts "must look at the totality of the circumstances." Yamanouchi, 231 F.3d at 1347. An ordinary case is certainly not "exceptional." Examples of "exceptional cases" for which the United States Court of Appeals for the Federal Circuit has awarded fees in typical patent infringement claims include "inequitable conduct before the PTO, litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement." Glaxo, 376 F.3d at 1350 (citing Hoffman-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1365 (Fed. Cir. 2000); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1548 (Fed. Cir. 1984)).

At this point, when and how a court may award attorney's fees in exceptional cases involving a willful infringement allegation may seem straightforward. It is not. Both parties cite Glaxo and Yamanouchi, but, of course, interpret and apply them differently. Because Glaxo explains Yamanouchi, the Court will examine Glaxo and its analysis of Yamanouchi in detail.

a. The Glaxo Opinions

In Glaxo, the Court of Appeals for the Federal Circuit reversed the district court's finding that the generic company's ANDA filing constituted willful infringement because the "mere filing of an ANDA cannot constitute grounds for a willful infringement determination." Id. at 1342. Unfortunately, to understand the scope of the appellate court's opinion and what "mere filing" might mean, one must look at the district court's opinion in the case in order to appreciate the case's specific facts.

i) The District Court's Glaxo Opinion

The district court in Glaxo concluded that Apotex, the generic company, had willfully infringed because "Apotex's ANDA filing [was] permeated by a lack of due care" and the "non-

credible trial testimony of Apotex's witnesses are classic examples of conduct that clearly and convincingly demonstrates willfulness." Glaxo Group Ltd. v. Apotex, Inc., 268 F. Supp. 2d 1013, 1033, 1034 (N.D. Ill. 2003). The district court first found that the CEO of Apotex, a Dr. Sherman, "never obtained an opinion of independent patent counsel on either non-infringement or invalidity in this case" and relied only on the "hearsay declaration of a hired expert witness" to justify the ANDA filing. Id. The district court found that filing an ANDA "without any legal analysis of [drug's] patent rights" to demonstrate a lack of due care. Id. at 1034.

The district court also observed that, "[f]aced with [the] admission of infringement in the application he drafted, Dr. Sherman labeled his statement a 'typographical error.'" Id. The district court went on to point out that "[t]his attempt to evade as 'errors' or 'mistakes' . . . was also the centerpiece of the testimony of another Apotex witness." Moreover, the person actually responsible for the statements, a Dr. Cappuccino, "disavowed any responsibility for the statements and characterized them as unauthorized," which the district court found to be not credible. Id. Finally, the district court described yet another witness, a Dr. Siegel, who "found the 'typographical error' to be a convenient explanation." Id. In the district court's view, these instances of non-credible testimony exemplified conduct that demonstrates willfulness. Id.

In addition, the district court was not persuaded by Apotex's argument that it did not act willfully because it did not provide a written certification when its ANDA was filed. The district court concluded its discussion by finding "the filing of the ANDA by Apotex triggered GlaxoSmithKline's infringement claim and constituted willful infringement in view of the circumstances described above." Id. at 1035 (emphasis added).

ii) The Court of Appeals for the Federal Circuit's Glaxo Opinion

The Court of Appeals for the Federal Circuit disagreed with the lower court's finding of willful infringement in Glaxo. Glaxo, 376 F.3d at 1349. It began its analysis by observing that filing an ANDA "constitutes a 'highly artificial' act of infringement." Id. It then explained the remedies available when a patent owner successfully shows infringement in the ANDA context, noting that attorney's fees may be awarded in exceptional cases. Id. at 1350. The appellate court went on to give willful infringement as an example of conduct constituting an "exceptional case" for the purposes of attorney's fees.

In addition to providing this example, however, the Court of Appeals for the Federal Circuit went on to explain it has "limited what types of conduct may give rise to an award of attorney's fees for the purposes [of the ANDA remedies in Section 271(e)(4)]." Id. It then discussed Yamanouchi, where it "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, which combined with litigation misconduct, warranted an exceptional case finding" but not a "willful infringement finding." Id. (emphasis added). While baseless ANDA filings, meritless arguments, and litigation misconduct may constitute an exceptional case finding for the purposes of attorney's fees, the Court of Appeals for the Federal Circuit squarely held that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for the purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." Id.

While the Glaxo holding is straightforward, the extent of its application is not, because the facts surrounding Apotex's conduct are not included in the appellate opinion. Reading the text alone, the fact that the Glaxo court used the word "mere" to describe the act of filing an ANDA application suggests that any action beyond "mere filing" is not included in its standard. Something more than "mere" is usually something different. Thus the following question inevitably arises:

could conduct beyond the "mere fact of filing an ANDA" support a finding of willful infringement for the purposes of attorney's fees?

As part of its rationale, the Court of Appeals for the Federal Circuit in Glaxo observed that the district court "did not find that Apotex engaged in any litigation misconduct, and Apotex did not file of paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity such as that filed in Yamanouchi."[2] Id. With respect to Yamanouchi, the Glaxo Court then observed that "the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in is case at trial and in its ANDA certification." Id. Accordingly, the Glaxo court explained, they determined in Yamanouchi that "a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." Id. at 1350. In this way, while the Glaxo court disagreed with the district court's "elevat[ion] of the ANDA certification into a finding of willful infringement," it also observed that the generic company's baseless ANDA certification accompanied by litigation misconduct appropriately resulted in an award of attorney's fees. Id. Consequently, after Glaxo, it appears to this Court that a district court may not "elevate" an ANDA certification, even if it is "baseless," into a finding of willful infringement for the purposes of attorney's fees; rather, a baseless ANDA certification accompanied by litigation misconduct may result in an award of attorney's fees because such conduct constitutes an "exceptional case." Aventis Pharma Deutschland GMBH v. Cobalt Pharm., 355 F. Supp. 2d 586, 591 (D. Mass. 2005).

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[2]Isn't every failed ANDA filing essentially baseless? As discussed infra, the Court is inclined to think so, which is why the Glaxo court appears to have been so concerned about limiting attorneys fees to only exceptional cases where a "wholly unjustified" and baseless ANDA filing is also accompanied by litigation misconduct. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350 (Fed. Cir. 2004).

Because Glaxo limited Yamanouchi, this Court suspects that the Glaxo court had the same concerns this Court had with the Yamanouchi decision. In Yamanouchi, the Court of Appeals for the Federal Circuit affirmed the lower court's decision to award attorneys fees as part of the "totality of circumstances" analysis for exceptional cases. It noted that the Defendants relied on a "legal opinion contain[ing] an acknowledged error in chemistry" and thus found that Defendants' ANDA filing lacked adequate foundation. Yamanouchi, 231 F.3d at 1347. The appellate court, unfortunately, did not include facts found in the lower court that mitigates what seems at first blush, to this Court at any rate, a harsh conclusion, as generally parties may rely on their lawyers' opinion as long as that reliance is reasonable and they adhere to the analysis in good faith. See Central Soya Co., Inc. v. Geo. A. Hormel & Co., 723 F.2d 1573, 1577 (Fed. Cir. 1983). The lower court's opinion in Yamanouchi, however, reveals that the lawyer who issued the opinion had a financial interest in the success of the ANDA application, as he would receive as a fee for his opinion "fifty percent of the 'Marginal Gross Profit' of any of the drugs' sales if its corresponding patent challenge was successful."[3] Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc., 21 F. Supp. 2d 366, 375 (S.D.N.Y. 1998). Given this lawyer's lack of objectivity and obvious bias, which the client was indeed very much involved, the appellate court's affirmation of the exceptional case finding becomes more clear.[4]

With these egregious facts in mind, and given that the appellate court in Glaxo clarified Yamanouchi to emphasize that an ANDA certification should not be "elevated" into a finding of willful infringement, looking at the facts found by the lower court in Glaxo only confirms this

[3]The old adage "look for the money" is often a useful way to understand such conduct.

[4]This Court has already seen similar types of problems of this nature with some lawyers. See X-It Products, LLC v. Walter Kidde Portable Equipment, Inc., 227 F.Supp. 2d 494, 547 (E.D.Va. 2002).

Court's view that even a baseless ANDA filing could not constitute an act of willful infringement, although a baseless ANDA filing could constitute an exceptional case. As described supra, the district court found that the generic company filed what turned out to be a baseless ANDA "without any legal analysis of [drug's] patent rights." Glaxo, 268 F. Supp. 2d at 1034. The district court also found the generic company's witnesses to not be credible. Id. at 1035. Yet the Court of Appeals for the Federal Circuit reversed the willful infringement finding. This strongly suggests that the "mere" filing standard protects a lot of willful conduct indeed surrounding the filing of an ANDA and therefore excludes willful infringement allegations in connection with the ANDA.

Moreover, the fact that the appellate court in Glaxo emphasizes that the purpose of the ANDA process is to create an "artificial" act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement. This is so because, as Glaxo explains, the purpose of the ANDA filing "is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." Glaxo, 376 F.3d at 1351 (emphasis added). If a generic company has not yet infringed the patent at issue because its infringement in filing an ANDA is only "technical" and "artificial" infringement for jurisdictional purposes, and if the resulting suit is a "hypothetical" one to determine if there would be infringement if the drug was marketed, Warner-Lambert, 316 F.3d at 1365, how could a patent holder accuse the generic company of willful infringement at all in the ANDA context if they can't allege a baseless ANDA filing? The Court is not sure how one could do it.[5] Indeed, as discussed infra, Plaintiffs' own facts demonstrate they

[5]Glaxo certainly suggests it is possible, as it gives willful infringement as one of its examples of instances where attorney's fees have properly been awarded. Id. at 1350. Glaxo appears, however, to be describing exceptional cases in patent law generally when it provides that example, and the lion's share of the opinion consists of a discussion of why the exceptional case analysis as opposed to willful infringement claims are appropriate in ANDA claims. In any event, as discussed

are unable to bring a willful infringement claim unconnected to Defendants' filing of a baseless ANDA.

Finally, the Court is compelled to observe that, given its understanding of the ANDA scheme, excluding allegations of willful infringement based solely on the filing of a baseless ANDA application serves the purposes of the scheme itself, which is clearly to encourage generic companies to participate in the ANDA process so that consumers may benefit from the faster availability of generic drugs. Ultimately, any generic company who loses its patent infringement suit after filing a paragraph IV certification has filed a "baseless" ANDA application. Indeed, it appears to this Court that its entire inquiry in this case will be grounded on the ANDA and whether or not Defendants are correct that the patent is invalid and/or will not be infringed. Thus it comes as no surprise to this Court that Glaxo restricts willful infringement claims supported solely by allegations of baseless ANDA applications. While this is so, generic companies may not file baseless ANDA applications with impunity. The Glaxo court is at pains to point out that particularly egregious conduct surrounding the filing of the ANDA and in the litigation itself could warrant attorneys fees as an exceptional case, and it uses Yamanouchi as an example. Glaxo, 376 F.3d at 1350-51. Should the Court find such conduct in this case, it will accordingly utilize the exceptional case analysis provided for by the statute and discussed in Glaxo.

b. Plaintiffs' Facts

While the Court has doubts that a patent holder may allege willful infringement at all in ANDA cases given the nature of the ANDA scheme, Plaintiffs' own pleading defeats the claim because all they allege is that Defendants willfully and deliberately filed a baseless ANDA.

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infra, even if such an allegation is possible, Plaintiffs' have not alleged facts beyond the filing of a baseless ANDA, which Glaxo prohibits.

Plaintiffs allege Defendants infringed the '722 by filing an ANDA application. Am. Compl. ¶ 20. Plaintiffs then allege Defendants "had notice of the '722 patent at the time of its infringement. [Defendants'] infringement has been, and continues to be, willful and deliberate." Id. ¶ 23. Plaintiffs go on to assert that Defendants' "Paragraph IV Certification, that in [its] opinion, the '722 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of [Defendants;] Ramipril Capsules is baseless." Id. ¶ 24. In this way, Plaintiffs' willful infringement claim rests, just as Defendants' contend, on the allegation that Defendants' willfully and deliberately filed a baseless ANDA application. This is exactly what Glaxo prohibits.

In Aventis Pharma Deutschland GMBH v. Cobalt Pharm, 355 F. Supp. 2d 586 (D. Mass. 2005), a district court reached this same conclusion under facts identical to facts before the Court here. In Cobalt Pharm, Plaintiffs alleged that the generic company willfully infringed the patent by "filing an 'utterly baseless' paragraph IV certification with the FDA." 355 F. Supp. 2d 586 (D. Mass. 2005) (quoting plaintiff's amended complaint). Cobalt, like Defendants here, filed a Rule 12(c) Motion asking that the willful infringement claim be dismissed. Relying on Glaxo, the district court granted Cobalt's motion, noting that "the only act of infringement alleged in Plaintiffs' amended complaint is Cobalt's filing of an ANDA and a paragraph IV certification with the FDA." Id. at 592. "Because this artificial act of infringement cannot be considered willful," the district court went on to explain, "Plaintiffs have averred no facts that can support a finding of willful patent infringement." Id. The same situation exists in this case. Defendants' Rule 12(c) motion to dismiss Plaintiffs' willful infringement claim is therefore **GRANTED** without prejudice to the Court later determining if this is a case is an exceptional one warranting a willful infringement determination based on the "totality of circumstances" and awarding attorney's fees.

c. Exceptional Cases

While it is clear from Glaxo that a willful infringement claim may not rest entirely on the "mere filing" of an ANDA application, even if that application is baseless, it is also clear that willfully filing a baseless ANDA application may be considered "misconduct" as part of the "totality of the circumstances" should attorney's fees be awarded as an "exceptional case." Glaxo, 376 F.3d at 1350; Yamanouchi, 231 F.3d at 1346-47; AstraZeneca Pharm. L.P., 2005 WL 2864666 at *28. Under Glaxo, district courts may consider willfulness, as long as the allegation does not rest on the mere filing of an ANDA application, as part of the "totality of circumstances" analysis for the purposes of attorney's fees. Glaxo, 376 F.3d at 1350. Even though the Court has dismissed Plaintiffs' willful infringement claim, the bottom line is that, should attorney's fees be merited in this case, the Court **ADVISES** the parties that this dismissal will not limit its ability to weigh the "totality of circumstances" should it find this case to be an "exceptional" one and attorney's fees merited. See Yamanouchi, 231 F.3d at 1347.

III. Conclusion

The Court concludes by observing that, in many respects, both parties make reasonable arguments based on their interpretations and applications of Glaxo and Yamanouchi. The opinions are difficult to reconcile but not impossible.[6] As pointed out supra, in Yamanouchi, the relied-on attorney's opinion was anything but disinterested. Even so, the Glaxo court emphasized that Yamanouchi's situation was an "exceptional case" and the district court should not have elevated the conduct surrounding the baseless ANDA application, which was based on the very interested and involved attorney's opinion, into a finding of willful infringement, but rather ". . . baseless filings

[6]By utilizing the district courts' opinions in both Glaxo and Yamanouchi, we can begin to reconcile the two decisions. Because the opinions failed to fully set out the facts in relation to the imposition of attorney's fees in both cases, reviewing the district courts' opinions in those cases makes the appellate court's results at least understandable.

supporting its fruitless and meritless arguments both in its case at trial an in its ANDA certification" merited exceptional circumstances. Glaxo, 376 F.3d at 1350. It is obvious that Glaxo intended to limit Yamanouchi because otherwise the expansion of Yamanouchi would eviscerate the ANDA process outlined in the statute. Unfortunately for Plaintiffs, Defendants are absolutely correct that Glaxo, the latest case on the subject by the Federal Circuit, squarely holds that a willful infringement claim may not be based solely on the filing of a baseless ANDA application. And that is all Plaintiffs have alleged. This Court will follow the latest case of the Federal Circuit. Accordingly, Defendants' Rule 12(c) motion to dismiss Plaintiffs' willful infringement claim is **GRANTED WITHOUT PREJUDICE** to its ability to consider whether or not this is an exceptional case and attorney's fees are merited pursuant to 35 U.S.C. § 285 and what may be the "totality of circumstances."

The Clerk is **DIRECTED** to send a copy of this Memorandum Opinion and Order to all counsel of record by mail and facsimile.

IT IS SO ORDERED.

/s/
ROBERT G. DOUMAR
UNITED STATES DISTRICT JUDGE

Norfolk, Virginia
January 18, 2006